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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,195	12/03/2003	Shan Lu	17738-003001 / UMMC 03-24	7308

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,195	LU ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-60 and 81-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-60 and 81-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Office acknowledges Applicant's amendment filed on May 19, 2006. Claims 1-52 and 61-80 are canceled. Claims 53-60 and 81-110 are pending and are examined in the instant Office action.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed on July 11, 2006 is attached to the instant Office action.

3. The rejection of claims 54-60, 81-93, 95-106 and 108-110 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicant's argument.

4. The rejection of claim 53 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement **is maintained**.

5. Claim 53 is broadly directed toward a method of treating an individual with AIDS, the method comprising administering to the individual a protein composition comprising a plurality of sets of HIV envelope proteins of a genetic clade in amount sufficient to inhibit disease progression due to HIV.

6. Applicant argues that the claimed invention provides utility and advantage over other vaccine candidates because of broader spectrum response induced by the polyvalent protein composition.

7. Applicant's argument is fully considered but found not persuasive. It is well

known in the art that development of therapeutic HIV vaccine remains a challenge. To date, no HIV immunogen has proven to provide clinical benefit to HIV infected patients although they can induce immune responses to the immunogen *in vivo*. The instant specification has not shown that the instant polyvalent protein composition can induce protective immunity, or control of viremia in an HIV infected patient. The state of the prior art has shown that development of a therapeutic vaccine against HIV infection is unpredictable. The plasticity of the HIV-1 genome and its contribution to immune escape are salient factors that have prevented the development of protective immunity in HIV infected patient. Even when a neutralizing antibody or CD8+ response is generated after immunization, it rapidly becomes ineffective as other members of the quasispecies quickly replicate and grow out.

8. Therefore, considering the broad scope of the claim, the complex state and nature of the art, unpredictability from the prior art, Applicant has not provided sufficient information to enable the full breath of the claimed invention without undue experimentation.

9. The rejection of claims 54-60, 81-90, 93, 97, 109 and 110 under 35 U.S.C. 102(a), as being anticipated by Barnett (1997), **is withdrawn** in view of Applicant's argument.

10. The rejection of claims 54 and 96 under 35 U.S.C. §103, as being obvious over Andre *et al.* **is withdrawn**.

11. The rejection of claims 54, in part, and claims 91, 92, 94, 95, 97 and 98 under 35 U.S.C. §103, as being obviousness over Barnett (1997) and Gao (1996) **is withdrawn**.

12. Following are new grounds of rejections:

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 54-60 and 81-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett (Vaccine, Vol. 15 (1997), No. 8, pp 869-873), Gao (*J. Virology* Vol.70 (1996), No.3, pp 1651-1667); *AIDS Res. Hum Retroviruses*, Vol. 10 (1994), pp 1359-1368) and Andre (*J. Virology*, Vol. 72(1998), No. 2, pp 1497-1503).

15. Claims 54-60 and 81-110 are directed to a method of inducing immune responses in a mammal comprising immunizing the mammal with multiple sets of HIV envelope DNAs and multiple HIV envelope proteins of different clades, wherein one of more of DNA vaccines comprises optimized codons.

16. Using BALB/c mice and Guinea pig as animal models, Barnett teaches a method of inducing immune responses using priming immunization with a DNA plasmid vaccine containing envelope genes of primary strains, HIV-1_{US4} (clade B) and HIV-1_{CM235} (clade

E), and boosted with their proteins. Both humoral and cell-mediated immune responses were tested. Barnett teaches that the DNA prime/subunit protein boost may be safe and less costly alternative vaccination strategy because the ability of HIV DNA vaccines to effectively and reproducibly induce immune responses. Barnett does not teach the use of multiple HIV envelope DNAs and proteins of different clades as immunogens.

17. Gao teaches a panel of envelope genes from HIV-1 primary isolates of clade A to G. Gao also suggests that the panel of envelope genes from HIV-1 clade A to G should prove valuable for AIDS vaccine development efforts targeted against a broader spectrum of viruses.

18. Andre teaches an HIV gp120 DNA vaccine whose gene codons are optimized for improved expression in human cells. Andre teaches that the DNA vaccine containing optimized codon usage considerably increases the gene expression in human cells, resulting enhanced immune responses in BALB/c mice.

19. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of Barnett, Gao and Andre in order to increase the breadth of reactivity of a HIV vaccine cross genetic clades and increase the immunogencity of the vaccine. One would have been motivated to do so, given the suggestion by Gao that envelope genes from HIV-1 clade A to G should prove valuable for AIDS vaccine development efforts targeted against a broader spectrum of viruses. There would have been a reasonable expectation of success that the polyvalent vaccine and codon optimized immunogen would generate enhanced immune responses, given the knowledge taught by Andre that codon optimized DNA vaccines have higher expression level in vivo and result in increased immunogenicity of DNA vaccines.

> MPEP § 2144.06 recites the conclusions of *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA), "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art."
>
> The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

20. Since the instant invention is drawn to combining some envelope genes and proteins of known HIV isolates to increase immune responses in a mammal, the combination of their additive effects renders the invention *prima facie* obvious and does not exhibit an unexpected result. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Remarks

21. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bo Peng, Ph.D.
8/4/06

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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